REMARKS

Claims 1-19, 21-35 and 39-57 are pending in the subject application. Claims 1 and 3 are amended to correct typographical errors.

Favorable reconsideration in light of the amendments are remarks which follow a respectfully requested.

1. Claim Objections

Claims 2 and 3 are objected to. The Office asserts that "these claims seem to be redundant in positively reciting 'a flexible cannula' and 'a second cannula' twice". Applicants have amended the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. 102 Rejections

Drasner et al.

Claims 1-4, 8, 12, 16, and 25-33 are rejected under 35 U.S.C. 102(b) over Drasner et al (USPN 5,234,406).

Applicants respectfully traverse.

Applicants recite, in claim 1, a microcatheter system for infusion of a solution into a retinal vein. Applicants' microcatheter system remains within the retinal vein during the infusion without an external holding device for at least a period of time required for a bolus injection. The microcatheter system further comprises a flexible cannula mounted in a second cannula, wherein the flexible cannula and the second cannula form an infusion fluid path.

Applicants recite, in claim 2, a microcatheter system comprising a flexible cannula for insertion into a retinal vein lumen and a second cannula. The flexible cannula is at least partially encased in the second cannula, and the flexible cannula and the second cannula form an infusion fluid path. Solution is infused into the retinal vein lumen through the flexible cannula and the

flexible cannula remains within the retinal vein lumen during the infusion without an external holding device for at least a period of time required for a bolus injection.

Applicants recite, in claim 3, a microcatheter system comprising a flexible cannula for insertion into a retinal vein lumen and a second cannula. The flexible cannula is mounted in the second cannula, and the flexible cannula and the second cannula form an infusion fluid path. A solution is infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding device.

Drasner, on the other hand, describes a method and system for delivery of anesthetics to the spine. Drasner's system includes a distal catheter section 12 and a proximal tube extension 14. Distal catheter section 12 has a lumen diameter ranging from 28 gauge to 32 gauge, and a length ranging from 15-25 cm. According to Drasner, the length of the distal catheter section 12 is minimized in order to reduce flow resistance and is long enough to accommodate insertion through a conventional spinal needle with minimum excess length. (See col. 3, lines 29-38) The proximal tube extension 14 has a lumen 26 with a diameter ranging from 20 to 22 gauge. Thus, Drasner's distal catheter section 12 (which the Office asserts is equivalent to Applicants' flexible cannula) has a lumen ranging from 28 gauge (0.0149", 0.38mm) to 32 gauge (0.0097", 0.25mm). The outer diameter of the distal catheter section 12, thus, is even larger than the lumen.

Applicants respectfully submit that the intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and Drasner. Applicants' microcatheter system is for infusion of a solution into a retinal vein, and it is designed such that the microcatheter system can remain within the retinal vein during the infusion without an external holding device for at least a period of time required for a bolus injection (see claim 1). According to claim 2, Applicants' microcatheter system comprises a flexible cannula for insertion into a retinal vein lumen, and it is designed such that solution is infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding device for at least a period of time

required for a bolus injection. According to claim 3, Applicants' a microcatheter system comprises a flexible cannula for insertion into a retinal vein lumen, and is designed such that a solution can be infused into the retinal vein lumen through the flexible cannula and the flexible cannula remains within the retinal vein lumen during the infusion without an external holding device. To provide such insertion into a retinal vein and infusion of a solution as claimed, the microcatheter system must be designed and sized appropriately. In particular, due to the small and delicate nature of the retinal veins, the microcatheter system must be sized such that the portion of the device inserted into the retinal vein (e.g. flexible cannula) is no greater than 100 μm/0.1mm (see e.g. page 9, lines 7-11; page 12, lines 8-12). Drasner's device, on the other hand, is specifically adapted for insertion through a patient's back and into the spinal area. Drasner's device provides a catheter having an outer diameter that must be at least 2.5 times as large as Applicants'. Drasner's device could not be used for insertion into a patient's eye and insertion into the retinal vein within the eye. Further, Drasner could not be modified so as to provide a device that could be inserted into the eye and retinal vein because such a modification would render the modified device unsuitable to be used as intended.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over Drasner. Claims 4, 8, 12, 16, and 25-33 depend from claims 1-3 and, likewise, are patentable over Drasner.

DeCamp et al

Claims 1-7, 12, 14-19, and 25-33 are rejected under 35 U.S.C. 102(b) over DeCamp et al (USPN 5,792,099).

Applicants respectfully traverse.

DeCamp describes a device for insertion of viscoelastic material into an eye. DeCamp's device includes cannula 24 and a needle 26. The needle includes a first large diameter portion 36 and a second smaller diameter portion 40. The first portion 36 is between 18 gauge (0.0478", 1.21 mm) and 23 gauge (0.0269", 0.68mm) (see col. 4, lines 42-44). The second portion 40 is

between 23 gauge (0.0269", 0.68mm) and 30 gauge (0.012", 0.31mm)(see col. 4, lines 44-47). Further, according to DeCamp, the length L_1 of first portion 36 ranges from 0.25 and 0.5 inch, and the length L_2 of the second portion 40 range from 0.25 and 0.5 inch.

As discussed above with respect to Drasner, Applicants respectfully submit that the intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and DeCamp. DeCamp's device provides a needle portion having an outer diameter that must be at least 3 times as large as Applicants'. Further, DeCamp could not be modified so as to provide a device that could be inserted into the eye and retinal vein because such a modification would render the modified device unsuitable to be used as intended. Applicants' respectfully submit that the viscosity of materials delivered by DeCamp (5,000 – 60,000 cp, as set out, e.g., in col. 4, lines 12-22) could not be delivered by cannula having sizes set forth by Applicants.

Further, Applicants respectfully submit that DeCamp's device could not be used for insertion into a patient's eye and insertion into the retinal vein within the eye because the lengths of the needle provided by DeCamp would not be capable of reaching the retinal vessels in the back of the eye when inserted through a standard pars plana incision because a typical human eye is about 2.5 cm in length. Further, DeCamp could not be modified so as to provide a device that could be inserted into the eye and retinal vein because such a modification would render the modified device unsuitable to be used as intended. DeCamp is specifically designed for the insertion of viscoelastic material into the eye, not the retina.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over DeCamp. Claims 4-7, 12, 14-19, and 25-33 depend from claims 1-3 and, likewise, are patentable over DeCamp.

Grinblat et al

Claims 1-7, 12, 14-16, 19, 21, and 23-33 are rejected under 35 U.S.C. 102(b) over Grinblat et al (USPN 5,545,153).

Applicants respectfully traverse.

Grinblat describes an illumination and infusion system that includes a tube 26 having a plate member 28 at its distal end. Extending from the other side of the plate member 28 is a cannula portion 29. The plate member is adapted to be sewn to the eyeball at the start of the operation. The cannula portion 29 has an outer diameter of 0.9mm and a length from 3.5-6.0mm (see col. 4, lines 14-21).

As discussed above with respect to Drasner and DeCamp, Applicants respectfully submit that the intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and Grinblat. Grinblat's device provides a cannula portion 29 having an outer diameter that must be at least 9 times as large as Applicants'. Further, the length of Grinblat's cannula portion would not provide a device capable of reaching the retinal vessels in the back of the eye when inserted through a standard pars plana incision.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over Grinblat. Claims 4-7, 12, 14-16, 19, 21, and 23-33 depend from claims 1-3 and, likewise, are patentable over Grinblat.

Le et al

Claims 1-4, 12-16, and 25-33 are rejected under 35 U.S.C. 102(b) over Le et al (USPN 6,355,027).

Applicants respectfully traverse.

Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief. The catheter tube 16 measures 100 to 160 cm long from the strain relief.

As discussed above with respect to Drasner, DeCamp, and Grinblat, Applicants respectfully submit that the intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and Le. Applicants' microcatheter system is for infusion of a solution into a retinal vein, and it is designed such that the second cannula is inserted into the eye and the flexible cannula, which extends from the second cannula, is inserted into a retinal vein lumen. The human eye is about 2.5 cm in length and, thus, Applicant's device is structurally designed for insertion of the second cannula through a pars plana incision such that the flexible cannula reaches the retinal veins. Le's device does not possess this structure, nor could it. Modification of Le so as to provide a device that could be inserted into the eye and retinal vein would render the modified device unsuitable to be used for insertion through and traversal of tortuous vascular paths because the device would not be long enough for such use.

Accordingly, Applicants respectfully submit that claims 1-3 are patentable over Le. Claims 4, 12-16, and 25-33 depend from claims 1-3 and, likewise, are patentable over Le.

3. 35 U.S.C. 103 Rejections

DeCamp

Claim 8 is rejected under 35 U.S.C. 103(a) over DeCamp. Applicants respectfully traverse for the reasons set forth above.

As set out, DeCamp describes a device for insertion of viscoelastic material into an eye. The intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and DeCamp. There is no teaching or suggestion to modify DeCamp to provide Applicants' device because of the differences between the Applicants' and DeCamp's device and how the different devices are used. These differences in use require different

structures and, thus, one of ordinary skill would not have been motivated to modify DeCamp because such modification would have rendered the modified device unsuitable to be used as intended.

Accordingly, claim 8 (which depends from claims 1-3) is patentable over DeCamp.

Le and Drasner

Claims 8-11 and 17-18 are rejected under 35 U.S.C. 103(a) over Le and Drasner. Applicants respectfully traverse.

As set forth above, Drasner describes a method and system for delivery of anesthetics to the spine. Drasner's system, thus, includes a distal catheter section 12 and a proximal tube extension 14 specifically designed for such delivery. Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief specifically designed for such insertion and navigation.

One of ordinary skill would not have been motivated to combine Drasner and Le. Drasner's device is specifically adapted to deliver anesthetics to the spine, while Le is specifically adapted for insertion into and through tortuous pathways. Further, even if Drasner and Le could be combined, neither Drasner nor Le teach or suggest Applicants' structure for insertion into the eye and retinal vein. No combination of Drasner and Le would provide Applicant's device. Still further, any modification of Drasner and Le would render the modified device unsuitable to be used as intended.

Accordingly, claims 8-11 and 17-18 (which depend from claims 1-3) are patentable over Drasner and Le.

Le and Applicants' Own Disclosure

Claims 19 and 21-23 are rejected under 35 U.S.C. 103(a) over Le in view of Applicants' own disclosure.

Applicants respectfully traverse.

As set forth above, Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief. The catheter tube 16 measures 100 to 160 cm long from the strain relief. The intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and Le. Le's device does not possess this structure, nor could it. Modification of Le so as to provide a device that could be inserted into the eye and retinal vein would render the modified device unsuitable to be used for insertion through and traversal of tortuous vascular paths because the device would not be long enough for such use. Modification of Le in view of Applicants' own disclosure would render the modified device unsuitable to be used as intended.

Accordingly, claims 19 and 21-23 (which depend from claims 1-3) are patentable over Le in view of Applicants' own disclosure.

Le and Castora

Claims 34-35 are rejected under 35 U.S.C. 103(a) over Le in view of Castora (USPN 5,947,296).

Applicants respectfully traverse.

As set forth above, Le describes a flexible microcatheter for insertion and navigation through tortuous vascular paths. Le's microcatheter includes a strain relief 14 and a catheter tube 16 extending from the strain relief. The catheter tube 16 measures 100 to 160 cm long from the

strain relief. The intended use of Applicants' claims 1-3 results in a structural difference between Applicants' claimed invention and Le.

Castora is merely cited as describing a catheter kit with multiple catheters packaged in one kit. Castora does not teach or suggest Applicants' microcatheter systems with the structural differences described herein. Further, even if Castora did provide such structural differences, one would not have been motivated to combine Le and Castora to provide such a structure because such modification would render the modified device unsuitable to be used as intended.

CONCLUSION

It is believed that the application is in condition for immediate allowance, and Applicants respectfully request early favorable action by the Examiner.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

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